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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/802,668 | 03/09/2001 | Steven L. Roberds | PHRM-0319 | 3061 |

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| EXAMINER |
|---|
| CHERNYSHEV, OLGA N |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/802,668 | ROBERDS ET AL. | |
| | Examiner | Art Unit | |
| | Olga N. Chernyshev | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-117* is/are pending in the application.

4a) Of the above claim(s) *1-94 and 97-116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95, 96, 117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

1. Claim 95 has been amended and claim 117 has been added as requested in the amendment of Paper No. 19, filed on July 29, 2003. Claims 1-117 are pending in the instant application.

Claims 1-94 and 97-116 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Claims 95, 96 and 117 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on July 29, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### *Claim Rejections - 35 USC § 101*

5. Claims 95, 96 and 117 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record as applied to claims 95-96 in section 7 of Paper No. 18. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein

encoded thereby. Because the instant application does not disclose the biological role of this protein or its significance, an antibody to the protein cannot be considered particularly useful.

Applicant traverses the rejection on the premises that the antibodies of the present invention can be used "to isolate and/or purify the protein from cells to identify other proteins" (page 28, first paragraph of the Response). Further, "the antibodies of the present invention can be used to modulate the activity of the ion channel or related variants", and also "[a]ntibodies can also be used to monitor expression of the polypeptide in an *in vitro* setting after transfecting a nucleic acid encoding a polypeptide comprising SEQ ID NO: 105 into cells". Applicant's arguments have been fully considered but are not deemed to be persuasive for the following reasons.

The instant claims are drawn to an antibody that binds to a polypeptide of as yet undetermined function or biological significance, polypeptide of SEQ ID NO: 105. In the absence of knowledge of the biological significance of this specific polypeptide of SEQ ID NO: 105 or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect, there is no immediately obvious patentable use for this polypeptide and, consequently, for the antibody that binds to an epitope of the polypeptide of SEQ ID NO: 105. The employment of the antibody of the instant invention for isolation and purification of proteins from cells is not a substantial or specific utility. Any antibody can be employed to detect or purify proteins by the virtue of its binding ability. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility. To grant Applicant a patent encompassing an isolated antibody to a naturally occurring human protein of as yet

undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*).

Applicant's arguments that "the claimed invention can be used to modulate protein activity, identify ligands and other binding partners, such as other proteins that interact with the polypeptide, monitor expression of the protein *in vivo* and *in vitro*" (page 29, first paragraph of the Response) are not persuasive for the reasons fully explained earlier. Briefly, at the time of the instant invention the biological significance of the polypeptide of SEQ ID NO: 105 lies in the knowledge that it is asserted to constitute an ion channel and, therefore, modulates a specific physiological activity in response to a specific signal. Since the instant specification does not disclose the identity of the signal or any particular association of this specific sequence with any biological process, knowledge of the changes in expression of that protein estimated by antibody binding is not particularly useful. Moreover, 35 USC § 101 clearly states that the invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. The fact that Applicant submits that some experimentation may be required to practice the claimed invention, such as "to identify binding ligands and other binding partners", simply confirms that the instant invention was not completed as filed, and, therefore, clearly lacks utility in currently available form.

Applicant further argues that "[I]n the present application homology is in excess of 40% over more than 70 amino acid residues. The probability, therefore, that the polypeptide encoded by the claimed polynucleotides is related to the reference polypeptides is, accordingly, very

high" (page 30, second paragraph of the Response). However, based on the percent similarity between the reference sequences, one skilled in the art would, at most, conclude that the instant polypeptide of SEQ ID NO: 105 belongs to the class of ion channels, which is known to include proteins with diverse physiological functions. Yet, in the absence of knowledge of the biological role of the instant polypeptide of SEQ ID NO: 105, there is no obvious patentable use for the antibody to this polypeptide. Therefore, since the instant specification does not disclose a credible "real world" use for the claimed antibody, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Finally, it is well settled that the prosecution of one patent application does not affect the prosecution of an unrelated application. *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976) (holding that "[I]t is immaterial in *ex parte* prosecution whether the same or similar claims have been allowed to others"). Accordingly, Applicant's arguments with respect to the other US Patents to ion channel proteins (page 31 of the Response) are unavailing.

***Claim Rejections - 35 USC § 112***

6. Claims 95, 96 and 117 are also rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 95-96 in section 8 of Paper No. 18. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 103***

7. Claims 95 and 96 and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isenberg et al. (Neuroreport, 1993, 5, pp.121-124) for reasons of record as applied to claims 95-96 in section 11 of Paper No. 18.

Applicant argues that "there is nothing in the Isenberg reference that would motivate a person of ordinary skill in the art to generate an antibody to the eight amino acid sequence that was identified by the Office as being identical to an eight amino acid sequence in SEQ ID NO: 105" (bottom at page 35 of the Response). This argument has been fully considered but is not deemed to be persuasive for the following reasons.

Because the amino acid sequence of 5HT3 receptor disclosed by Isenberg et al. comprises an epitope of eight consequent amino acids, which completely match an epitope of SEQ ID NO: 105, an antibody generated against the sequence, which comprises this epitope, would also bind the polypeptide of SEQ ID NO: 105 of the instant invention. Such antibodies would be encompassed by claims 95, 96 and 117. One of ordinary skill in the art would be motivated to generate antibodies against 5HT3 receptor using the entire receptor sequence, which would include the epitope identical to SEQ ID NO: 105.

***New grounds of rejection necessitated by amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 117 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 117 is vague and indefinite for recitation "specific for SEQ ID NO: 105". The metes and bounds of the recitation cannot be determined form the claim or the instant specification because it is not clear if the specificity is defined by binding to a specific epitope, or to a protein from a particular species, or both.

***Conclusion***

9. No claim is allowed.

10. This application contains claims 1-94 and 97-116 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC
September 15, 2003

JOHN ULM
PRIMARY EXAMINER
GROUP 1800